Section 5: 510(k) summary K121471

Date Prepared: 28 June 2012

JUL 10 2012

Submitters name, address, telephone, fax, and contact person:

LightScalpel LLC
16932 Woodinville-Redmond Rd NE Suite 201
Woodinville, WA 98072
425-408-9477
425-487-1157 fax
Gerald S. Palecki, General Manager

Product Trade Name: LightScalpel family of handpiece tips for CO_2 surgical lasers

Product common names: Accessory laser tips

Classification names: Laser surgical instrument for use in general and plastic surgery and in dermatology, 21CFR 878.4810, product code GEX . Panel: General and plastic surgery devices,

Legally marketed predicate device: Aesculight family of fibers, handpieces, and tips for CO_2 surgical lasers. (K081612)

Device description: These tips are short, hollow lightpipes of alumina ceramic or stainless steel that provide a variety of spot sizes to target tissue when utilized in a mating laser handpiece.

Intended use: The intended use is to communicate the laser beam of a CO_2 surgical laser to the target site for the incision, excision, ablation, or photocoagulation of soft tissue. Representative examples of indications for use:

Gynecology—excision and vaporization of cervical, vulvar, and perineal condyloma; ablation of vaginal and vulvar intraepithelial neoplasia; herpes vaporization; vaporization of urethral caruncle; I&D Bartholin's and nubothian cysts.

Dermatology – port wine hemangioma removal; rhinophyma reduction; telangiectasia removal; wart removal; basal squamous cell carcinoma removal; blepharoplasty; xanthalasma removal; removal of neurofibromas hemangiomas, nevi, and tircoeptiheliomas; dermabrasion for lentigos, keratosis, actinic keratosis and actinic cheilitis.

Dentistry/Oral Surgery – gingivectomy; frenum release; gingivoplasty; removal of soft tissue, cysts, and tumors

General Surgery – hemorrhoid removal; skin tag vaporization; pilodidal cyst removal and repair; debridement of deciditus ulcers and stasis ulcers; mastectomy; breast

biopsy, reduction mammoplasty; cyto-reduction for metastatic disease; many dermatological procedures.

Laparoscopic surgery – vaporization, incision, excision, ablation, or photo-coagulation of soft tissue such as endometriosis ablation, excision of adhesions, salpingotomy.

Otorhinolaryngology – lymphangioma removal; turbinectomy, subglottic stenosis vaporization, tonsillectomy, removal of vocal cord papillomas, nodules, and polyps.

Podiatry – plantar wart vaporization; fungal nail treatment; partial and complete matrixectomy; porokeratoma ablation; Morton's neuroma removal; ingrown toenail treatment

Orthopedic – menisectomy, chondromalacia ablation, partial synovectomy, lateral release, PMMA removal

No new indications for use are sought beyond those associated with the predicate device.

Summary technological characteristics and comparison to Predicates: These products are identical to the predicate products, utilizing the same specifications, materials and methods. The only difference between these products and the predicates is the final sterilization method and the attendant packaging and labeling. The sterilization method changes from user steam sterilization with the predicate to pre-sterilized radiation sterilization with the submitted devices. Both sterilization methods demonstrate the ability to sterilize to 10^{-6} SAL.

Nonclinical Performance Data: Data were provided relative to the validation of sterilization parameters required for obtaining 10^{-6} SAL utilizing radiation sterilization.

Clinical Performance Data: None

Conclusion: The submitted devices are substantially equivalent to the predicate devices with identical construction and performance with validated sterilization to 10^{-6} SAL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LightScapel, LLC
% Mr. Gerald S. Palecki
General Manager
16932 Wood-Red Road Northeast Suite 201
Woodinville, Washington 98072

JUL 10 2012

Re: K121471
Trade/Device Name: LightScalpel family of handpiece tips for CO_2 surgical lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 14, 2012
Received: May 18, 2012

Dear Mr. Palecki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known):

Device Name: LightScalpel family of handpiece tips for CO_2 surgical lasers

Indications for Use:

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Prescription use __Yes__ AND/OR Over-The-Counter Use __No__
(Part 21CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121471